

REMARKS

Reconsideration of the present application, as amended, is respectfully requested, in view of the remarks that follow. This application, as amended, includes claims 39-53, 57, 60, 74-76 and 87-94, pending and under consideration.

At the time the outstanding Office Action was mailed on August 10, 2006, claims 39-53, 57-60 and 74-82 were pending and under consideration and claims 61-73 and 83-86 had been withdrawn from consideration. Claims 58-59, 61-73 and 77-86 have now been cancelled, without prejudice. New claims 87-94, all of which are dependent claims, are presented herein for entry into the application. Claims 39-53, 57, 60, 74-76 and 87-94 stand rejected. Reconsideration of the present application, in view of the above amendments and the remarks herein, is respectfully requested. For the reasons set forth herein, the Applicant submits that, and respectfully requests an indication that, pending claims 39-53, 57, 60, 74-76 and 87-94, as amended, are in condition for allowance.

Claim Amendments

As an initial matter, based upon a number of statements in the outstanding Office Action, Applicant observes that the wording “substantially free from propellant gases” entered into the claims by Applicant’s Response dated May 26, 2006, was not interpreted by the Examiner in the manner intended by Applicant. In order to obviate the misunderstanding, Applicant has removed this language from the claims, and alternate language has been entered. In particular, upon entry of the above amendment to claim 39, each of the pending claims recites an atomizing spray dispenser that “is not an aerosol device.”

In addition, in an effort to streamline the examination of this case, and thereby facilitate movement of the case to allowance, Applicant has also cancelled multiple claims, without prejudice, and presented amendments whereby each of the pending claims specifies that the diaper rash treatment composition includes a solid particulate material. Applicant submits that the prior art does not teach or suggest the delivery of a diaper rash treatment composition including a solid particulate material using a non-aerosol system, and that the amended claims therefore patentably distinguish the cited art, as discussed more fully below.

Election/Restriction

In the outstanding Office Action, a restriction requirement is made based upon an assertion that, “Newly submitted claims 83-86 are directed to an invention that is independent or distinct from the invention originally claimed.” In support of the restriction, the Action states that, “the invention claimed in new Claims 83-86 and the originally claimed invention are related as combination and subcombination.” Applicant disagrees with the restriction requirement; however, in an effort to minimize issues in the present case, and thereby hasten the allowance of this case, Applicant has mooted this issue by cancelling claims 83-86.

Claim Rejections – 35 USC §112, first paragraph

In the outstanding Office Action, claims 39-53, 57-60 and 74-82 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Action indicates that the wording in the claims “substantially free from propellant gases” introduces new matter. Without acquiescing in the rejection or the assertions in the Action in support thereof, Applicant submits that the rejection is mooted by the above amendments, whereby some of the rejected claims have been cancelled, and the wording “substantially free from propellant gases” is removed from the remaining claims. Upon entry of the amendments, the pending claims are drawn to methods that involve the delivery of diaper rash treatment compositions using a dispenser that “is not an aerosol device.” The claims, as amended, are definite and satisfy the written description requirement of 35 U.S.C. §112, first paragraph. Specifically, the wording added to the claims by amendment find support at page 25, line 15 to page 26 line 7 of the specification.

Claim Rejections – 35 USC §112, second paragraph

In the outstanding Office Action, claims 39-53, 57, 59, 60 and 74-82 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Without acquiescing in this rejection or the assertions made in support of the rejection, Applicant

submits that the rejection is overcome by the above-presented amendments, whereby the wording “substantially free from propellant gases” is removed from claim 39; the wording “to leave a relatively drier coating on the skin treatment area” is removed from claim 76; and wherein claims 77, 78, 79 and 82 are cancelled. In view of these amendments, Applicant submits that the claims satisfy the requirements of 35 U.S.C. §112, second paragraph, and respectfully requests withdrawal of this rejection.

Claim Rejections – 35 USC §103

In the outstanding Office Action pending claims 39-53, 57-60 and 74-82 stand rejected as being unpatentable under 35 U.S.C. §103(a) over various combinations of references. In particular, claims 39-50 and 57-60 are rejected in the outstanding Action as being unpatentable over European Patent Application Publication No. 191 128 by Adams et al. (hereafter “the Adams reference”) in view of U.S. Patent No. 4,816,254 to Moss (hereafter “the Moss reference”) and U.S. Patent No. 5,536,502 to Mulder (hereafter “the Mulder reference”); claims 41-43 and 60 are rejected under 35 U.S.C. §103(a), as being unpatentable over the Adams reference in view of the Moss reference and the Mulder reference, and further in view of U.S. Patent No. 6,103,247 to Boussouira et al. (hereafter “the Boussouira reference”); claims 39, 51 and 52 are rejected under 35 U.S.C. §103(a), as being unpatentable over the Adams reference in view of Noubourg (WO 99/08649 as translated by U.S. Patent No. 6,423,323); claim 53 is rejected under 35 U.S.C. §103(a), as being unpatentable over the Adams reference in view of Noubourg (WO 99/08649 as translated by U.S. Patent No. 6,423,323) and further in view of the Moss reference; claims 76, 79 and 82 are rejected under 35 U.S.C. §103(a), as being unpatentable over the Adams reference in view of U.S. Patent No. 6,103,245 to Clark et al. (hereafter “the Clark reference”); and claims 39, 58, 59, 74, 75 and 77-81 are rejected under 35 U.S.C. §103(a), as being unpatentable over the Adams reference in view of the Moss reference and the Mulder reference and further in view of U.S. Patent No. 5,436,007 to Hartung et al. (hereafter “the Hartung reference”).

Applicant submits that each of the combinations of references asserted in the outstanding Office Action, and listed above, is overcome because the primary reference cited

in each combination, the Adams reference, describes an aerosol delivery system and each of the pending claims in the present application, as amended, recites an atomizing spray dispenser that is “not an aerosol device.” As such, the combination of any other reference with the Adams reference, such as, for example, the selection of ingredients from the cited secondary references for modification of the composition described in the Adams reference, still results in a delivery system that delivers a composition using an aerosol delivery mechanism. In fact, the Examiner stipulates in the Action at page 10 that the Adams reference teaches “‘aerosol-type’ diaper rash formulations” and does not teach “the claimed atomizing spray delivery mechanism such as pump spray dispenser.” As such, Applicant submits that each of the combinations cited in the Action, each of which relies upon the Adams reference as the primary reference, fails to support a rejection of the pending claims pending in the present application, as amended, because each of the combinations would result in an aerosol-type delivery system. Applicant therefore submits that the recitation in independent claims 39, as amended, of an atomizing spray dispenser that is “not an aerosol device” overcomes said rejections for at least this reason.

It is worthy of note that some of the claims rejected in the outstanding Office Action (i.e., claims 74, 75, 77, 78, 80 and 81) were drawn to subject matter that excluded aerosol delivery mechanisms. For example, claim 74 recites that, “the atomizing spray delivery mechanism is selected from the group consisting of an atomizing pump spray dispenser and a pressure release device.” The other identified claims also specify certain atomizing spray delivery mechanisms that are distinct from aerosol systems. The only combination of references that was asserted in the outstanding Action in support of a rejection of claims 74, 75, 77, 78, 80 and 81, was a combination of the Adams reference in view of the Moss reference and the Mulder reference and further in view of the Hartung reference. As mentioned above, the Examiner stipulates in the Action at page 10 that the Adams reference teaches “‘aerosol-type’ diaper rash formulations” and does not teach “the claimed atomizing spray delivery mechanism such as pump spray dispenser.” In support of the rejection of claims 39, 58, 59, 74, 75 and 77-81, the Action states that:

While teaching “aerosol-type” diaper rash formulations, Adams et al. do not explicitly teach the claimed atomizing spray delivery mechanism such

as pump spray dispenser. However, Hartung et al. teach applying diaper rash lotion by means of “a spray from an aerosol or pump dispenser” as well as by other means. See col. 5, lines 10-13; col. 13, lines 37-41.

The Examiner appears to be suggesting in the above-quoted statement that an aerosol dispenser and a pump dispenser would be interchangeable; however, Applicant strongly disagrees with this implication. While aerosol delivery and pump spray delivery might be interchangeable mechanisms for delivery of compositions that are highly thinned (i.e., very low viscosity), it is important to note that the subject matter of the pending claims of the present application, as amended, is directed to unique compositions that include a solid particulate material, and that have a specified combination of physical properties whereby, upon application of a coating of the composition to a skin treatment area, the coating “does not run off the skin treatment area.” The cited references do not describe any compositions that meet the recited properties of sprayability and run-off resistance, that include solid particulate material and that are delivered using a non-aerosol spray delivery mechanism, as recited in the pending claims of the present application, as amended. Applicant submits that neither the Hartung reference, nor any other reference of record, teaches or suggests this unique combination of features.

Moreover, Applicant submits that a person of ordinary skill in the art at the time the present application was filed would not have had an expectation that he or she could successfully provide a “diaper rash treatment compositions of Adams et al. in view of Moss and Mulder” that would be sprayable “by means of a pump dispenser” as suggested in the Action at page 10. In particular, no expectation of success can be derived from mere identification in the prior art of ingredients in a diaper rash treatment composition having significantly different physical properties and delivered using significantly different delivery mechanisms. Rather, there would be no expectation upon consideration of the prior art that any combination of ingredients described therein would have the properties of sprayability and run-off resistance recited in the pending claims. The rheological properties necessary to provide a spray dispensation system capable of atomizing a diaper rash treatment composition including a particulate solid material without having propellant gases entrained therein, while also providing for retention of the composition on the skin treatment area after

delivery, are not taught, described or suggested in the cited references, nor are these features exhibited by the compositions described therein. This is clearly supported in the declarations submitted with Applicant's prior response, which are of record in the present case.

In addition to the above, the nonobviousness of the claimed subject matter is supported by the fact that multiple embodiments of the application have been recognized by experts in the relevant field as being breakthrough technology and a significant advance in the field. Indeed, as set forth in the Cawthon declaration, products encompassed by the pending claims won the top vote award at the MedAssets' New Technology Fair in October 2005, at which 47 preselected high-tech healthcare companies presented their new products. The panel of judges of the competition was composed of independent, neutral, technical specialists in various disciplines, including skin and wound care specialists. The grading criteria (based on a 4.00 scale) used by the judges were as follows, and the scores of the Applicant's sample compositions that are within the scope of the pending claims are set forth in parentheses:

Vendor's technology...	<i>Applicant's score</i>
- is new and can be considered "breakthrough" technology	4.00
- will have a significant impact on improving patient care	3.93
- will have a significant impact on improving labor efficiency	3.91
- will have a significant impact on improving cost efficiency	3.84
- will benefit the MedAssets' contract portfolio	3.81
-	

Applicant's Overall Score: 3.90 (#1 out of 47 companies)

Attached to the Cawthon declaration is a copy of the letter reporting the above-described result and detailing this information. Applicant submits that this evidence also strongly supports the non-obviousness of the claimed subject matter.

In view of the above, Applicant submits that the combination of the Adams reference in view of the Moss reference and the Mulder reference and further in view of the Hartung reference does not support a rejection of the claims of the present application, as amended, under 35 U.S.C. §103. Withdrawal of this rejection is therefore respectfully requested.

Remarks Regarding Other Statements in the Action

While not necessary for purposes of overcoming rejections, Applicant also provides some additional brief remarks for the record to address other statements in the outstanding Action, as follows.

First, with regard to the evidentiary effect of Rule 132 declarations, Applicant submits that it is improper for the Examiner to ignore the information included in the three Rule 132 declarations submitted with Applicant's prior response. Moreover, the Office Action does not present an acceptable explanation for ignoring them.¹ The Examiner asserts in the Action that each of the declaration of Shishir Shah and the declaration of Dean O. Harper is entitled to little weight because "the declaration is a mere statement of the opinion and does not present any experimental data in support of that opinion." In reply, however, Applicant submits that the lack of experimental data in a declaration is not a sufficient reason to ignore the evidence in the declaration. Moreover, the Examiner has provided no authority for the suggestion that a declaration must provide experimental data in order to be entitled to weight. Section 716.01 of the MPEP states that, "Evidence traversing rejections, when timely presented, must be considered by the examiner whenever present." Applicant submits that the declaration of Shishir Shah and the declaration of Dean O. Harper each includes a significant amount of information regarding, for example, how spraying a composition using propellant gas-based aerosol technology is significantly different than spraying a viscous composition using non-aerosol atomizing spray mechanisms, how a person of ordinary skill in the art would understand the teachings of various references, what the teachings of various references would or would not motivate a person of ordinary skill in the art to do, and the like. In addition, it is clear from the credentials of the Declarants that the information provided in the declarations is technically valid.

In view of the above, Applicant submits that the Examiner must consider the information provided in the declarations. Section 716.01 of the MPEP also states that,

¹ While the Examiner suggests that the declarations are given "little weight," there is nothing in the Action to suggest that any of the evidence presented in any of the declarations was given any weight at all in the Examiner's review of the application.

“Where the evidence is insufficient to overcome the rejection, the examiner must specifically explain why the evidence is insufficient. General statements such as ‘the declaration lacks technical validity’ or ‘the evidence is not commensurate with the scope of the claims’ without an explanation supporting such findings are insufficient.” Because the Examiner has provided no acceptable explanation for ignoring the evidence in declarations, and no authority by which she is entitled to summarily dismiss this information, Applicant submits that the information in each of the declarations, which is uncontroverted in the record, must be accepted at face value for what it states.

With regard to the Cawthon declaration, the explanations provided by the Examiner for ignoring this declaration are also insufficient. The first explanation provided by the Examiner is that “the results demonstrated in the declaration are not commensurate in scope with the instant claims.” As per Section 716.01 of the MPEP, set forth above, this statement is insufficient. Moreover, Applicant submits that the Cawthon declaration is not submitted to provide any proof that would require experimental results “commensurate in scope” with the claims. Rather, one significant purpose of the declaration is to explain the disclosure of the Mulder reference, namely, to show that the formulation disclosed in Table 1 of the Mulder reference does not have the physical characteristics recited in the pending claims of the present application. In so doing, Applicant also provided multiple examples of formulations within the recitations of one or more claims; however, this information was not required information, and was simply provided as a frame of reference for purposes of comparison. As stated in paragraph 4 of the Cawthon declaration, “Applicant has determined that the composition described in Mulder does not have the properties described and claimed in the present application.”

The Action also states that, “More specifically, the Applicant tested compositions containing specific ingredients present at the specific concentrations, while the instant claims (with the exception of Claim 47) do not recite any concentrations and do not recite any specific formulations.” This statement appears to suggest that experimental data would NEVER be commensurate in scope with any claim reciting a composition if the claim does not specifically recite the exact ingredients in exact concentrations. It is believed that this implication finds no support in any law, regulation, rule or precedent,

and none was cited in support thereof. Applicant would note for the record that it is impossible to make or test any composition that does not have specific ingredients present at specific concentrations. In fact, there does not exist a composition that does not have specific ingredients at specific concentrations. Therefore, Applicant submits that this statement is also an insufficient explanation for ignoring the declaration.

The next explanation provided in the Action for ignoring the Cawthon declaration is that, “the Mulder patent is not the closest prior art and was used as a secondary reference to supplement the teachings of Adams et al. and Moss et al.” This, however, is not a valid reason for ignoring a declaration. Moreover, Applicant submits that because the Adams reference describes only aerosol systems that use propellant gases entrained in a composition, and the Moss reference describes ointments that cannot be delivered by atomizing spray delivery, there is significant question regarding whether these references are any “closer” than the Mulder reference. Nevertheless, the Examiner’s opinion of which reference is “closest” is not a valid reason for discarding evidence submitted in a timely filed declaration.

The Examiner also asserts that the experimental data set forth in the declaration is flawed because it is “inconsistent with the reference’s clear and explicit teaching, and the issued US patents enjoy the presumption of validity.” In this regard, the Examiner implies that the data in the Cawthon declaration is flawed because Dr. Cawthon heated the composition to 50°C. The Action asserts that, “Since Mulder does not mention heating the medicament to 50°C before applying it to the wound, and such step would be contrary to both common sense and good medical practice, it is reasonable to assume that the composition of Mulder is used at the room temperature.” (Office Action, Page 12). Applicant agrees with this statement, but submits that the Examiner’s interpretation of its significance is incorrect. The Action appears to suggest that Dr. Cawthon’s heating of the composition somehow destroyed its physical properties that would enable it to be sprayed. To the contrary, however, the Examiner overlooks the statements at paragraph 15 of the Cawthon declaration that, “The Mulder composition had a consistency that resembled pancake batter at 50°C and a thick paste at room temperature. The liquid was sprayable at 50°C but not at room temperature, and thereby failed the sprayability test.”

(emphasis added). These statements make clear that the composition at room temperature was not sprayable, but rather had the consistency of a thick paste.

In view of the information presented in the Cawthon declaration, Applicant submits that the Mulder patent does not describe a composition that meets the limitations of the pending claims because the composition described therein does not have the sprayability feature recited in the pending claims. Moreover, while it might be possible to modify the composition described therein to make it sprayable (for example, by increasing the concentration of water and decreasing the concentration of spray-resistant ingredients), there is no description therein of a composition that can be sprayed and that does not run off of a skin treatment area, as recited in the pending claims, nor are there any descriptions that would suggest how to make a composition having such properties.

At page 13-14 of the outstanding Action, the Examiner questions certain statements made on or about page 20 of Applicant's prior response. In reply, Applicant regrets any confusion that may have resulted from the prior statements, and provides the following additional remarks in an effort to clarify. The main point that Applicant wishes to make regarding the Mulder reference is that it includes inconsistent teachings regarding the physical properties of the formulation described as "Spray Liquid Medicament." In particular, the Mulder reference states at column 5, line 65 to column 6, line 1 that, "The mechanical action of spray liquid permits a complete flushing of the wound site to soften and rinse away debris from the wound," but yet inconsistently states at column 6, lines 5-7 that, "The viscosity of the medicament is...high enough to prevent substantial free liquid runoff subsequent to application." A composition simply cannot have physical properties that permit "a complete flushing of the wound site to soften and rinse away debris from the wound" and also have a "viscosity...high enough to prevent substantial free liquid runoff subsequent to application." In view of the clear inconsistency in the statements of the Mulder reference, Applicant submits that it provides no clear teaching regarding any physical properties of the composition described therein. Moreover, as described in the Cawthon declaration, Dr. Cawthon produced the formulation specifically described in Table 1 of the Mulder reference to determine what

physical properties it did indeed have. The result of this testing, as reported in the Cawthon declaration, is that the formulation is not sprayable.

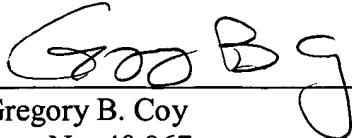
As one final matter, the Examiner also states at paragraph 16 of the Action that, “Upon cancellation of the new matter, the rejection over Gebhart will be reinstated.” Applicant submits that the rejection over Gebhart asserted in a prior Office Action is not a proper basis upon which to reject the present claims, as amended, for the same reasons that the rejections relying upon the Adams reference are overcome. Specifically, the Gebhart reference describes aerosol systems that are not encompassed by the pending claims, as amended.

Closing

In view of the above, Applicant respectfully submits that the rejections stated in the outstanding Action are overcome and that the present application, as amended and including claims 39-53, 57, 60, 74-76 and 87-94, is in condition for allowance. Action to that end is respectfully requested. If there are any remaining issues that can be addressed telephonically, the Examiner is invited to contact the undersigned to discuss the same.

Respectfully submitted,

By: _____


Gregory B. Coy
Reg. No. 40,967
KRIEG DeVAULT LLP
One Indiana Square
Suite 2800
Indianapolis, IN 46204-2079
Tel.: (317) 636-4341
Fax: (317) 636-1507

KD_IM-847064_2.DOC